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ABSTRACT

This report supports amending the proposed Federal Trade Commission (FTC) Rule on Over-the Counter (OTC) Drug Advertising to insure better protection for children, illiterate populations, the deaf and the blind, from advertising on the air-waves. Several points are addressed: (1) the difficulties of combining the rule making schedules of the Food and Drug Administration (FDA) and the FTC; (2) the nature of OTC advertising and labeling, particularly for large child audiences; (3) behavioral studies on techniques of television commercials; (4) ambiguous interpretations of FDA language on the part of those regulated; and (5) the vulnerabilities of the functionally illiterate, the deaf, and the blind. (DAG)

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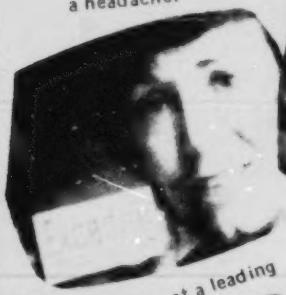
MAN: Would you just keep one thing in mind about diarrhea.

This difference is the extra pain relieve that Anacin provides when you have a headache.

I know it's gonna work.



The other at a leading university.

It gives the old one two — the old one two.

WOM: Have I got something for a backache.

helping your child to sleep so you can too.

IR 004 702

TO THE FEDERAL TRADE COMMISSION
IN THE MATTER OF
A TRADE REGULATION RULE
ON OVER-THE-COUNTER DRUG ADVERTISING

Roger Fitzpatrick
Presiding Officer
February 26, 1977

BEST COPY AVAILABLE

Submitted by:

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PREFACE

This testimony is being presented to the Federal Trade Commission as a result of funding provided by the Magnuson-Moss Warranty--Federal Trade Commission Improvement Act (93-637). The Council on Children, Media and Merchandising (CCMM) first sought funds a year before the over-the-counter (OTC) drug hearings were scheduled; we regret that this funding did not become available until 2 1/2 weeks before the deadline for submission of remarks. The time element precluded our identifying and preparing individual witnesses, researching the total literature, and analyzing all the complicated interactions of the Federal Trade Commission and the Food and Drug Administration. We nonetheless submit these views in behalf of children and those with reading disabilities, those with hearing disabilities, and on occasion, the blind. This paper supplants the summaries previously submitted on February 3rd and February 7th which were distributed to the interested parties.

DIGEST

The Council on Children, Media and Merchandising enters these proceedings to seek amendments to the proposed Trade Regulation Rule (TRR) on Over-the-Counter Drug Advertising to ensure better protections for children, illiterate

populations, the deaf and the blind from advertising on the airwaves. We point out the difficulties of combining the rulemaking schedules of the Food and Drug Administration and the Federal Trade Commission. We point out the differences between OTC drug labels and advertisements, and the language therein. We describe the nature of OTC drug advertising, and the audiences it affects. For drug advertising in front of large child audiences, we seek strong constraints, until research shows they are unaffected.

We then address the techniques of television commercials, and the public's ignorance of the techniques; we cite behavioral studies which should be understood by the FTC as it seeks this rule, and recommend the FTC establish a panel to review how OTC drug messages will be perceived with FDA's language, or with sponsors' alternate language. We point out the grey areas where FTC's rule does not address the qualifying adjectives and phrases which may greatly influence the message's meaning. We stress the need for balance between advocacy, indications for use and warnings. We cite the FDA's panels' concern with such matters. We show how the self-regulation codes misrepresent their protections for children from drug advertising.

We remind the FTC of past advertising excesses in the OTC drug field, and point out the need for precise, but well understood, advertising messages. We stress the vulnerabilities of the functionally illiterate, the deaf and the blind. We seek audio and video messages of all critical aspects of the drug label's content.

We ask for an interim Rule to notify the public that the drug products, their labels and their advertisements are undergoing meaningful change. We ask for several technical changes in the Rule and drafted in order that these special populations will be better protected by the Rule.

INTRODUCTION AND BACKGROUND

My name is Robert Choate. I am Chairman of the Council on Children, Media and Merchandising. It is incorporated as a non-profit organization in the District of Columbia. The Council members advise me on child-related issues which arise from time to time.

I am not a pharmacist, doctor or lawyer. I am not a trained professional in advertising. My association with the advertising of products, particularly those seen on television, extends back some eight years to the White House Conference on Food, Nutrition and Health. As a result of initiating and serving as a senior staff member of that gathering, I have come to understand sponsor, advertiser and broadcaster approaches to selling goods and services over the air. I have become familiar with the data of A. C. Nielsen Company, Arbitron and Broadcast Advertisers Report.

I have had extended exposure to the problems of the disadvantaged and under-educated in the United States, having initiated programs with such groups since 1958 in many parts of the United States, particularly the Southwest. I have had exposure to the problems of Native Americans, the Spanish-surnamed, and others whose transient life or economic circumstances leave their vocabulary and education inadequate for full

participation in our society. I have enjoyed support from the President's Committee on Juvenile Delinquency, the Office of Economic Opportunity, the Ford Foundation, other foundations, and a number of Federal programs and agencies. Through repeated contact with those with inadequate education, I have come to see the role that television plays in their lives, and in the lives of their children.

My exposure to drug issues is more recent. In 1971 I read that the Director of FDA's Bureau of Drugs, Dr. Henry Simmons, estimated that 17,500 tons of aspirin were consumed yearly in this country. He questioned the role of advertising.[1/] Preoccupied with nutrition, I put off analyzing this phenomenon until 1974 and 1975 when my Council on Children, Media and Merchandising was twice the beneficiary of grants from the Drug Abuse Council. We studied who knew what about children's attitudes towards drugs and drug selling. I was a consultant to the House Communications Subcommittee in 1975 as it prepared for hearings on the subject of advertising hazardous products in front of children via television. Through the Council I joined in the petition of Massachusetts Attorney General Francis Bellotti wherein he and 16 other State Attorneys General asked the Federal Communications

Commission to set restraints on over-the-counter drug advertising prior to 9:00 p.m. The Council also participated in the staff hearings of the Federal Trade Commission and Federal Communications Commission on the subject of licit and illicit drugs and their consideration by children. In the above mentioned endeavors and in our long term advocacy of nutrition reforms, particularly food advertising, we have come to know many of the nation's top behavioral scientists who have studied children's responses to television.

At another level, the Council has had intimate involvement with FDA's over-the-counter drug review efforts. Since January, 1975, we have appeared before some six OTC panels reminding the expert panelists that the reforms that they were advocating in both product ingredients and product claims would have an influence on advertising, since the sponsors themselves were taking the labels and their packages into the advertisements, particularly those on television. In the discussion which ensued in those panel meetings it was very apparent that most of the panel members realized they had a responsibility to comment on the ability of advertising to dilute or corrupt their well-intentioned work on the labels of over-the-counter drugs. Several of the panel reports that have emerged or are emerging give evidence of the panelists' concern with advertising of drugs.

More recently the Council has been involved with the Federal Trade Commission in its promulgation of the Trade Regulation Rule on Food/Nutrition Advertising. In an effort to improve that rule we interviewed innumerable behavioral scientists on the subject of television and children. We sought witnesses. We interrogated advertising, industry and expert nutrition witnesses. We sponsored original research. Some of this pertains to adults with communication problems as well as children.

Over the last four years we have regularly petitioned the FTC and FCC to pay greater attention to advertising on television, particularly to vulnerable audiences. Through these moves we have some understanding of the law, and its limitations, in regard to protecting some of our most vulnerable citizens.

Finally, as a member of the National Advisory Committee to the Food and Drug Administration, I have come to understand the walls that separate Federal agencies, as well as the complications of FDA's OTC drug review.

Over the years we have become sensitive to the problems of those with hearing impairments and sight impairments who nonetheless are affected by television. We have sought out

experts in these areas and have asked those with hearing or sight impairments to speak for themselves, or submit statements.

Our constituency in this proceeding, therefore, includes over 40 million children under the age of 12; 4 million adults who are functionally illiterate; 14 million people with hearing impairments; and approximately 472,000 individuals with impaired eyesight, so impaired as to need help in reading a label even with glasses, according to the National Federation of the Blind.

THE FDA/FTC INTERFACE--THE FDA

> Recommendation: The Federal Trade Commission should recognize the different schedules of the Food and Drug Administration and the FTC, and issue an interim Rule as part of of this Rule to cope with the public's need to know over-the counter drugs are changing.

Since 1972, the Food and Drug Administration has been reviewing almost 500,000 over-the-counter drug products by various therapeutic categories to determine the safety and effectiveness of the 300-500 ingredients that comprise these products.[2/] (A trial run earlier had shown perhaps 75 percent were mislabeled, ineffective, or both.) The FDA, according to Dr. Sherwin Gardner, also having the legal responsibility to review labeling of these products, has asked various panels of nationally known

medical and health experts to review the conditions under which a therapeutic category of OTC drugs is safe and effective for the conditions indicated on the label. Symptomatic relief as distinct from cures has been studied. The reports that have emanated and will emanate from the panels of experts become monographs outlining the substantive regulations for the proper labeling of over-the-counter drugs upon their adoption by the Commissioner of the Food and Drug Administration after appropriate public proceedings have taken place. These monographs set the basic standard by which the Food and Drug Administration will regulate the bulk of non-prescription drugs in the United States in the future.

The monographs classify ingredients and claims into three categories. Category I includes those ingredients and claims (and related conditions of use, such as dosage levels and combinations of ingredients) that the panel concludes are generally recognized as safe and effective and not misbranded on the basis of existing data and information. These recommendations are embodied in a recommended monograph. Category II includes those ingredients and claims that the panel concludes are not generally so recognized. Category III includes those ingredients and claims for which the panel

concludes that data are insufficient to place them in either Category I or Category II and for which further testing is therefore required, i.e., ingredients and claims that the panel concludes are capable of being generally recognized as safe and effective and not misbranded if further testing is performed. The report which leads to the monograph contains a detailed explanation of the reasons for the panel's recommendations. It also recommends a period of time during which products with ingredients or claims in Category III may continue to be marketed pending the completion of further testing. Most reports contain detailed guidelines for such testing. One product can have Category I, II and III ingredients of claims.

The 17 different panels that are reviewing 26 categories of OTC drugs for the FDA have a specific protocol for their work. The reports that are suggested by the expert panelists do not automatically become substantive regulations, but are subject to review and revision by the Commissioner of the Food and Drug Administration in a lengthy administrative process. The FDA's process has already been underway for five years. We believe that the process will not be concluded for another five years. The FDA has published five panel reports, the first on administrative procedure, the

others covering some 13 major therapeutic categories and approximately 30 pharmacological groups, but only two monographs have been finalized. It is very likely that the promulgation and processing of these latter two administrative stages may take as long as two or three years for each therapeutic category. Further, because of the controversy that will ensue, one can expect the drug manufacturers to challenge at least some of the FDA monographs in court, and thus their real effectiveness may be postponed even longer.

A timetable for final submission by panelists to the Commissioner of the Food and Drug Administration seems to be at this point as follows:

PMS STATUS REPORT
OVER-THE-COUNTER (OTC) DRUG EVALUATION PROJECT
ACCOMPLISHMENT OBJECTIVES

Panel/Document	MILESTONES				
	NAR	PM	TFM	FM	ICP
Antacids	1-73	4-5-73	11-12-73	6-4-74	10-7-76
Antimicrobial I	7-74	9-13-74	3-77	3-78	9-78
Internal Analgesics	11-76	4-77	4-78	4-79	10-79
Cough, Cold, Allergy, Bronchodilator and Anti-asthmatic Products	2-76	9-76	9-77	9-78	3-79
Sedative, Sleep-Aids and Stimulants	8-75	12-75	3-77	3-78	9-78
Topical Analgesic, Anti-rheumatic, Otic, Burn and Sunburn Products	5-77	9-77	9-78	9-79	3-80
Dentifrice and Dental Care Agents	6-77	10-77	10-78	10-79	4-80
Laxatives, Antidiarrheal, Emetic and Antiemetics	1-75	3-75	3-77	3-78	9-78
Hemorrhoidal Products	6-77	10-77	10-78	10-79	4-80
Contraceptives and Other Vaginal Products	4-77	8-77	8-78	8-79	2-80
Ophthalmic Products	3-77	7-77	7-78	7-79	1-80
Vitamins, Minerals and Hematinics	3-77	7-77	7-78	7-79	1-80
Oral Cavity Products	6-77	10-77	10-78	10-79	4-80
Antiperspirants	7-77	11-77	11-78	11-79	5-80
Miscellaneous Internal	12-78	4-79	4-80	4-81	10-81
Antifluorient	4-77	8-77	8-78	8-79	2-80
Miscellaneous External	12-78	4-79	4-80	4-81	10-81
Antimicrobial II	9-77	1-78	1-79	1-80	7-80
Topical Antibiotics	8-76	2-77	2-78	2-79	8-79

Note: Accomplished dates underlined; (NAR) receive non-adopted report as information copy; published in the FEDERAL REGISTER, (PM) proposed monograph, (TFM) tentative final monograph, (FM) final monograph, (ICP) issue compliance program.

The extent of this work -- from 10/76 to 10/81 -- indicates that even without considering court challenges, the FDA review of over-the-counter drugs is an extended and complicated operation.

THE FTC

Since 1938 the Federal Trade Commission has had responsibility for regulating over-the-counter drug advertising. It has done so on a selective basis, as certain dubious claims came to public attention. In the past, advertising of such products as Doan's Pills, Hudson Vitamins and Listerine has led to some rules, some consent decrees, and some increased awareness in the OTC drug industry as to the FTC's perception of proper drug promotion. FTC's piecemeal effort became obsolete, however, as FDA panelists started to make their categorical recommendations. In fact, the FDA panelists' work deciding what ingredients are ineffective and hence not approved for use in an OTC product and the FDA's evaluation of erroneous claims made many in the FTC aware, that, after the FDA review, advertisements for the first time could be judged on the basis of Federally reviewed scientific facts. Since the products are

changing and their labels are changing, it is proper that advertisements now change to report proper usage, and reveal to the public that the changes are important.

Having no particular expertise in pharmacology, the FTC decided to await the FDA panel monographs, and act on the advertising aspects of them as they emerged. The FTC decided to split its approach into two efforts: One deals with all affirmative claims, and is the subject of this proceeding; the other will deal, monograph by monograph, in a series of rulemakings, with the warnings and contraindications to be required for each category of OTC drugs. (The antacid monograph, now finalized, is the subject of present FTC Trade Regulation Rule on warnings.)

The issue here, then, is to what degree the FDA's OTC monographs should control the advertising of OTC drugs in print and on the air. Is label language the only language suitable for advertisement language? A major problem here is the timing of the FDA panels and their monographs, and the timing of the FTC and its dual rulemaking schedule. The catalyst here is the sponsors' use of the label/package in advertising of OTC drugs. In so doing sponsors have triggered joint involvement by both FDA and FTC as the following section demonstrates.

THE PACKAGE-LABEL/ADVERTISEMENT INTERFACE: THE LABEL

The FDA's Acting Commissioner, Dr. Sherwin Gardner, in his submission to the FTC in these hearings, has said:

> "The labeling must tell the consumer what the drug is for, how long it may safely be taken, how much of it may safely be taken in a period of time, and the manner in which it must be used to obtain the desired therapeutic effect."

He also stated that:

> "OTC labeling must provide information necessary to the safe and effective use of the product 'in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.'" (emphasis added) 3/

To the FDA, over-the-counter drugs are meant to provide symptomatic relief of generally self-limiting maladies, and are designed for self-selection and self-administration. Thus the labels are carefully drafted. To an advertiser, since there are so many competing OTC drug products to alleviate basically the same symptoms, ready identification of a particular OTC drug product by the casual seeker, becomes the primary goal. Thus OTC sponsors use the talents of label and package designers to stress the container configurations which one can readily identify on a pharmacy counter, a medicine cabinet shelf, or in a toilet article kit. The design of

the label, the color of the bottle, or the shape of the container seen in the advertisement can be the most important link to a customer's choosing the product.

With either perspective of the label, several facts are clear. The name is affixed to the product. The label contains the name of the manufacturer who is responsible for the label's message as well as the contents. The label is probably read when the consumer-to-be is interested in the product. If the consumer is slow of reading, or distracted, the phraseology of the label remains with the product, and can be looked at time and time again. If different members of the family should use the product differently, the information is on the label.

Dosages and warnings, being part of the label, are so connected to the affirmative persuasive portions of the message as to constitute an indivisible communication coupling affirmative advocacy and cautionary advice. The label appropriately serves a precise and balanced purpose for an interested consumer at a time when the consumer's interest in the product is high. This was and is FDA's purpose as it brings change to OTC marketing.

THE ADVERTISEMENT

An advertisement has a totally different purpose. According to Paul Harper, Chairman of the Board of Needham, Harper and Steers, an advertising agency with principal offices in Chicago, New York and Los Angeles while testifying in the Food/Nutrition hearings in Washington:

> "It is my belief that all advertising can hope to do in this increasingly cluttered advertising communication environment is to present the one salient feature of a product that best fits into a prospective customer's life, and I can't over-emphasize the need for simplicity and single-mindedness and directness in advertising communications if advertising is to remain an effective and economic business tool . . .
>
> All any commercial can do is establish a predisposition." (Emphasis added)

According to Thomas Dillon, then President of Batten, Barton, Drustine and Osborne:

> "Advertising is boldly and openly persuasive of a point of view which is clearly identified with the advertiser -- one of the few forms of persuasion in which the interest and the source of persuasion are always clearly labeled. Usually the intent of advertising persuasion is to influence a brand decision."
>
> To the FTC 10/22/71 in behalf of Joint ANA-AAAA Committee

According to Herbert Maneloveg, then Executive Vice President of McCann-Erickson, Inc., another advertising agency:

> "Media is one of the two basic components of an advertising effort. The first, to create a compelling sales message that helps establish or reaffirms a positive attitude toward a product or service.
>
> . . . And second, to determine who the prime customers might be and then to select vehicles in a way that the best prospects for a product or service are reached enough times to foster awareness of the copy claim." (Emphasis added. October 29, 1971, ibid.

The 1971 FTC advertising hearings repeatedly revealed that ad agency executives thought most successful commercials had a single focus, a single message. The food/nutrition TRR hearings just concluded had witnesses who repeated this argument. In OTC advertising the single focus is on the name of the product, and sometimes a mention of the ailment for which it is to be used.

We anticipate that advertising witnesses in these proceedings will raise the same argument. They will claim they cannot mix the name of the product with conditions for use and contraindications and warnings without destroying the value of the advertisement. We disagree. Multiple message commercials abound in television. "Piggybacking" is a term indicating that two or even three commercials are linked in a 30 second message. Pet food advertisements, as was pointed out in the food/nutrition hearings, stress many points of nutrition, coat, appearance, health and love. Premium mention

in dry cereal commercials is a classic example of dual message commercials. Hence we contend that the single emphasis of OTC commercials on the label name and sneeze or ache produces an incomplete message to the viewer and reflects a sponsor's desire to project an incomplete message to a viewer. In a field so related to the public's health, this is an unfair and deceptive practice.

There may be situations where all the conditions for use and all the contraindications and warnings cannot be included in a television commercial. In such cases it becomes imperative that the viewer of the commercial be led to the label with a strong motivation to read and understand it. Deprecating or diluting the advice to read the label therefore becomes even more misleading and deceptive. Examples will follow.

For the child viewing the OTC drug commercial the problem is even more critical. While the child may respond more to a parent's advice about OTC drug taking, the heavy repetition of OTC drugs to children, without comprehensible warnings, becomes a counter message to any parental cautionary influence. 4/**

**Evidence that sponsors seek out children to want pills is ditticult to discover in corporate files. But it does exist. On March 10, 1972, S. Land and A. Krulwich of the law firm of Arnold and Porter wrote to Robert Pitofsky, Director of the Bureau of Consumer Protection of the FTC on behalf of Hoffman-LaRoche, Inc.-Sauter Laboratories in reference to the company's advertising of vitamin and mineral supplements to children. They said, in part:

> "The reason why advertisers promote vitamin and mineral supplements to children is to make their consumption more palatable and more acceptable to them...In addition to making vitamin supplements in more palatable and attractive forms, Sauter believes that it is important to advertise them to children to insure that they are not regarded as medicines to be avoided. In the company's view, it would not be sufficient to advertise to parents to insure their acceptance by children."

Children are generally warned by parents about drug taking. But even children with skepticism, and educated adults, do not understand the sophistication of a television commercial's design. Dr. Kenneth George O'Bryan, Director of Ontario TV's Research Laboratories recently said:

> "In spite of controversy at a highly specific and technical level the overwhelming weight of research evidence points to a conclusion that television has begun to challenge print itself as a medium of information and comparative behavioral exchange . . .
>
> In general terms it can be demonstrated that the TV commercial is the most parsimonious method of establishing a single-dimensional attitude, belief or concept yet developed. Furthermore, there is ample evidence that commercial type messages, once learned, are highly resistant to erosion through memory loss and are amenable to many repetitions without loss of impact or acceptability. When the commercial is linked conceptually and/or affectively with the program it carries, or with the known or assumed qualities of its actors or theme, its potential for teaching and retention increases.
>
> In effect, the TV commercial is the single best method of mass implantation of an idea, belief, or short-sequenced behavior pattern yet devised." 5/

A television commercial viewer may be part of an audience in all conditions of alertness, sobriety and literacy.

In drug advertising etching the name of the product on the viewer's mind is critical. To accomplish this the sponsor highlights the name of the product but varies the setting to keep the viewer interested. The advisory message, on the other hand, not being of value in increasing sales, is relegated to a subordinate position, often having no connection to the scenario. It is to be forgotten.

By their own acknowledgement designers of television commercials seek to implant messages which will be remembered the next time one thinks of a need for such as food or drug. Constant reminding is the name of the game.

ADVERTISING: HOW MUCH TO WHOM?

To show the nature of OTC drug advertising we here summarize 1975 advertising budgets in all media. Note the network and spot percentages of dollars committed out of substantial budgets:

media expenditures compared in 1975

In measured media only, grouped by industries

AD RANK	COMPANY	TOTAL $(000)	% of Total Dollars: Newspapers	Gen'l Mags.	Farm Pub.	Spot TV	Net TV	Spot Radio	Net Radio	Outdoor
	Drugs and cosmetics									
4	Bristol-Myers	139,955.0	0.7	16.2	—	14.7	64.1	4.1	0.2	—
5	American Home Products	126,847.1	1.4	3.3	0.3	26.5	64.4	3.5	0.6	—
13	Warner-Lambert Co.	68,602.5	0.7	1.0	—	21.9	68.9	2.0	5.5	—
14	Sterling Drug Co.	67,050.5	0.5	5.4	0.3	15.8	69.7	4.3	4.0	—
16	Gillette Co.	66,846.1	—	7.2	—	21.8	69.8	0.9	0.3	—
31	Schering-Plough Inc.	43,261.7	—	11.7	0.3	21.3	57.3	1.3	5.9	2.3
34	Miles Laboratories Inc.	37,137.3	—	0.5	—	29.1	65.4	0.9	4.1	—
35	Johnson & Johnson	36,804.7	—	14.7	—	17.3	67.4	0.6	0.1	—
47	Morton-Norwich Products	32,817.8	—	9.0	0.4	21.8	67.3	0.6	0.9	—
51	Chesebrough-Pond's Inc.	28,516.6	3.9	14.6	—	12.5	60.6	1.5	6.9	—
64	Richardson-Merrell Inc.	24,671.8	0.6	9.5	—	18.1	65.8	3.8	2.2	—
69	Block Drug Co.	22,616.9	—	8.7	—	20.0	71.3	—	—	—
70	Revlon Inc.	22,129.3	—	26.9	—	27.3	45.3	0.2	0.3	—
71	SmithKline Corp.	21,743.7	—	8.1	0.9	10.7	55.7	11.2	13.1	0.3
83	Noxell Corp.	18,477.0	—	9.7	—	39.8	44.1	5.1	1.3	—
87	Pfizer Inc.	17,418.0	—	21.8	6.5	8.0	62.7	1.1	—	—
90	Carter-Wallace Inc.	17,296.4	—	3.5	—	5.1	90.5	0.9	—	—
94	Squibb Corp.	15,807.5	—	5.2	—	26.1	58.9	9.8	—	—

Advertising Age, August 23, 1976

To bring this into sharper focus, we herewith report on network cumulative budgets for the first nine months of 1976, according to Broadcast Advertiser Reports:

	Commercials	(Millions) Dollar Est.
Head Remedies, Sedatives, Sleeping Products	5,361	$ 65.4
Cough Cold and Sinus Remedies	3,839	45.9
Digestive Aids, Antacids	1,667	27.3
Laxatives	876	5.9
Vitamin Preparations and Tonics	1,438	18.2

To sharpen further insights on the intensity with which OTC drugs are advertised on the air, we here report on network advertising patterns for the full year 1976:

	Commercials	Cost
Anacin Products	1,055	$20.9 million
Excedrin Products	1,342	13.3 "
Bufferin	935	11.8 "
Bayer Aspirin	660	7.8 "
Dristan Products	479	10.1 "
Contac Cold Tablets	433	7.3 "
Hold Cough Suppr.	334	5.2 "
Alka Seltzer	540	11.5 "
Rolaids	395	5.7 "
Geritol	565	14.6 "
One-A-Day Vitamins	476	5.3 "

Note that these are network figures only, and do not include the vast amounts --perhaps another 33%, one third-- spent on spot advertising.

In the fourth quarter of 1976, Broadcast Advertiser Reports indicate that the following products had advertising patterns from which we draw the following conclusions:

American Home Products' Anacin had 120 commercials during the week-day daytime hours hitting the soap opera--(or is it the drug opera?)--audience; 13 commercials on Saturday/Sunday during sports and 119 commercials during the nighttime including such popular child watched shows as:

Bionic Woman +*	Jeffersons #
Happy Days +*	Phyllis
$6 Million Man +	Sanford and Son#
Good Times#	Chico and the Man#
The Waltons#	

Sterling Drug heavily aimed their Bayer Aspirin commercials at the soap opera and game show audiences (211) but also included the child-watched Waltons#, Sanford#, and Chico# programs.

American Home Products aired 139 Dristan Commercials with 76 commercials during Monday-Friday daytime soap operas and game shows and 63 commercials at night including:

Bionic Woman+*	The Jeffersons#
Happy Days +*	The Waltons#
$6 Million Man+	Emergency+
Welcome Back Kotter	Little House on the Prairie+*#

---

* In top 10 for women in audience
\+ In top 10 for children in audience
\# In top 10 for women or men over 50 in audience

Nabisco's Geritol is heavily advertised during the evening (118), and many commercials appear on:

Good Times#
Phyllis
Emergency+
Little House on the Prairie+*#
Chico and the Man#

Miles Laboratory, once famous for selling its Flintstone Vitamins on children's weekend programs, now pushes its One-A-Day Vitamins on the soap operas and game shows (122), but includes some evening efforts near:

Bionic Woman+*
Donny and Marie+
$6 Million Man+
Emergency+
Little House on the Prairie+#

Neilson summaries show that daytime programs have largely female audiences, with large numbers of the senior citizen group and many children under school age also watching. The early evening audiences include large numbers of children; e.g., Happy Days, 15.4 million; The Bionic Woman, 14.2 million; and The Six Million Dollar Man, 9.4 million.[6]

IMPLICATIONS FOR CHILDREN

Recommendation: Over-the-counter drug advertising in front of substantial child audiences shall be eliminated or carry strong warnings comprehensible to children.

Atkin, the Lewises, Kanter and Robertson, Rossiter and Kakkar have shown that children have varying responses to over-the-counter drug commercials.[7] There seems to be a positive link between their attitude toward using such products and advertisements for same, but it is not strong. No causal relationship has been proven or disproven.

As reported recently to the National Science Foundation by a team analyzing child TV research, Dr. Atkin (1975) examined the relationship between children's "medicine advertising exposure"--an index constructed by multiplying

amount of viewing evening television by degree of attention to sample OTC advertisements--and beliefs about medicine and its efficacy. Atkin's sample consists of 256 fifth, six and seventh grade children selected from schools in urban, sub-urban and small town areas in Michigan.

His results may be summarized in terms of the following advertising exposure-belief relationships, all of which are based on sixth-order partial correlations. These results should be interpreted as tentative given the order of magnitude of the correlations.

- Perceptions of reality. Children with high exposure to medicine advertising perceive that people are more often sick (r=.14) and that they more often take medicine (.14).
- Belief in medicine. High medicine advertising exposure correlates with the child's belief in the quickness of relief after taking medicine (.10).
- Illness concern. Children with high exposure to medicine advertising worry more about getting sick (.14).
- Approval of medicine. The relationship between medicine advertising exposure and approval of medicine is .12.
- Medicine efficacy. Children with high exposure are more likely to feel better after taking medicine.
- Medicine usage. There is a general lack of relationship between medicine advertising exposure and medicine usage (.03).

They will remain tentative until more research is undertaken.

In general these results suggest that medicine advertising exposure does, to a certain extent, influence the child's conceptions of illness and medicine.[8] These relationships tend to be accentuated somewhat among the smarter children (as measured by scholastic performance) and among the higher social status children. Other variables such as age and sex of the child, parental attitudes toward medicine, or the child's frequency of illness all show inconsistent results.[9]

A similar study to the Atkin study in concept is that of Lewis and Lewis (1974). A Pediatrics abstract of their works says:

> ABSTRACT. Fifth and sixth grade students in two elementary schools were requested to watch television and describe several commercial "messages" related to health. Children were asked for their conclusions (inferences), if they believed the message, and if either they or their parents used the product advertised. Two hundred and eight students believed 70% of 781 commercials viewed. Forty-five percent of the children had used the product advertised, and 55% of their parents were said to be users. Of the children, 47% were "true believers" (accepting all messages as true). Personal experience and parental modeling behavior (use) increased the credibility of the messages. The frequency of use of advertised products and acceptance of the messages as true was higher among children from lower socioeconomic backgrounds. Pediatrics, 53:431, 1974, TELEVISION COMMERCIALS, IMPACT ON CHILDREN.

Presuming there are more functional illiterates among those with lower socioeconomic backgrounds, we note here the credibility afforded advertisements on television merely

because they are on television. A segment of the public apparently thinks such messages have undergone official review. Only with this Rule will that misbelief become corrected.[10/]

Kanter (1970) found that students in fifth, seventh and eleventh grades reported their belief that advertising influences their feelings toward medicine. No evidence was obtained as to actual attitudinal effects. Many also thought that other young people were potentially capable of being influenced by OTC commercials. However, drug commercials were not recalled more easily than other commercials and has a low salience to the students (i.e., not talked about much). The youngest children (fifth grade) were the most believing of drug commercials. They were most receptive and least critical, suggesting that it is at this age level that drug commercials may have great potential impact.[11/] This could also indicate that skepticism increases with age, a finding generally confirmed in previous research by Ward (1971) and by Robertson and Rossiter (1974).[12/] Rossiter finds parents to be a far more influential force than television commercials. Liebert, et al., have shown disclaimers and directions for use frequently are over the heads of children.[13/] (The often cited Milavsky and Oxtoby-Smith studies are on post-12 year olds, and hence seem of lesser value here.)

The research needs are obvious. The report to the National Science Foundation recommends that the following research questions be investigated:

- Exposure. To what levels of proprietary medicine advertising are children actually exposed and how does this vary by age of the child? How much of this exposure occurs while the child is alone versus in the presence of a parent?

- Attention. Do children pay attention to proprietary medicine commercials or does "selective perception" operate to screen-out such advertising? What factors affect attention level--age of the child, the child's health history, parents' in-home usage of OTC drugs?

- Understanding. Do children understand OTC commercials? What meanings do they take from the commercial and how aware are they of the product's value under what conditions? What factors affect comprehension levels?

- Viewing Level. Do heavy users of television hold different attitudes toward OTC drugs than light viewers, when age and health history are controlled? How does viewing level affect receptivity to OTC drugs, realism of health, concept, and awareness of advantages and disadvantages (side effects) of OTC drugs?

- Usage. To what extent do parents administer OTC drugs to their children? To what extent do children request OTC drugs and is this associated with viewing level? At what age do children begin to self-administer OTC drugs?

- Multiple Sources. How do alternative information sources about OTC drugs interrelate and what specific roles do they play? Can the role of OTC advertising be separated in its impact from the role of parents, peers and teachers?

To this list we would add: To what degree do parents explain advertisements to children, and does their explanation, or non-explanation, influence a child's receptivity to an OTC drug advertisement?

These questions are indicative of the lack of knowledge concerning children and proprietary medicine advertising. It is questions such as these which must be answered in order to formulate meaningful policy concerning the advertising of OTC products to children. We also note that no one has research which indicates what the viewing of 1,000 drug commercials (our estimate) yearly does to the health beliefs of a child. The parents' conduct with over-the-counter drugs is no doubt critically important.

We do not mean to downplay the huge volume of research which shows the impact of television in general on children. The Rand Corporation's recent publication Television and Human Behavior; The Key Studies, George Comstock, Editor cites 145 studies on children of less than high school age.

There is a more general behavioral aspect to this--one which applies to all TV commercials. Dr. Barbara Fowles Mates, Research Director for the Electric Company of Children's Television Workshop fame, has studied how children may be influenced by more than just the phraseology of a commercial. Speaking relative to children, but citing research on a broader segment of the public, she said:[14/]

> "Some of the research on aggression suggests the presence of adult male models increases the likelihood that the child will imitate. Adult male models often occur as authority figures in drug ads. The research also suggests that when the actor is reinforced for his action (as the drug taker is demonstrably reinforced by relief from whatever ailment he is suffering) the child's imitative behavior increases. Finally, of course, the child who sees his parents taking the drug advertised or similar ones gets a double dose of the modeling and condoning behavior which ought to increase the likelihood of imitation."

Dr. Mates then quotes the findings of James P. Flanders:[15]

> "Research findings indicate that the more the child is presented with a reward for his responses similar to the model(i.e. greater reinforcement) the more he exhibits imitative behavior, while punishment decreases his degree of imitation. Children can also experience rewards vicariously. Thus, observing the model being reinforced has the same effect upon the child as receiving direct reinforcement, i.e. the likelihood of imitation increases. Both direct and vicarious reinforcement encourages imitation, but even when neither the child nor the model receive reinforcement, the child may still imitate the model. Offering the child incentives for producing previously prohibited behavior also acts to lower his inhibitions. The effect of live models on imitative behavior are more enduring over time, but there are no substantial differences in children's degree of imitation after observing live or filmed adult cartoon models. Even though children may not imitate a model immediately after the observation period, there is evidence that they can acquire the behavior patterns demonstrated and exhibit them at a later period."

In our telephone conversation on February 9, 1977, Dr. Flanders reaffirmed his belief that his statement might extend to OTC drug commercials partly because children may imitate a model's behavior even where no reward is shown.[16]

Rossiter on the other hand, feels that the child, to respond affirmatively to an over-the-counter drug commercial, must feel the reward will be as much or more for the viewer (i.e., the child), and not just for the person in the commercial.[17] While any commercial showing relief of symptoms within 30 seconds of taking a pill--the scenario of many over-the-counter drug ads--can be interpreted as giving the viewer a vicarious reward, we find one current commercial to be so crass in its suggesting a reward to children that we think it may transcend Dr. Rossiter's skepticism. Here is the storyboard and transcript of Needham, Harper and Steers for Bristol-Myers' Congespirin:

Radio TV Reports

41 East 42nd Street New York N.Y. 10017
(212) 697-5100

PRODUCT	CONGESPIRIN COLD TABLETS FOR CHILDREN		7F1340
PROGRAM	GAMBIT	9/22/76	30 SEC.
	WCBS-TV	(NEW YORK)	11:08AM

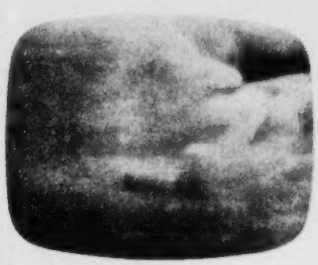
1. WOMAN: All set? Now blow. (SFX)

2. WOMAN: Uh uh. Blow out. (SFX)

3. Not with your mouth, your nose.

4. ANNCR: When your child has a cold Congespirin Cold Tablets for Children can help relieve sniffles and stuffy noses to make breathing easier.

5. Plus Congespirin reduces fever and pain fast.



6. WOMAN: How does your nose feel now?

7. BOY: Better mommy.

8. ANNCR: Congespirin, relieves stuffiness, reduces fever fast.

Needham, Harper and Steers
COPY

VIDEO SEQUENCE: "Close-up of little boy about 4 years old with mother holding handkerchief to his nose. Kid looking at mother. Move in to Extreme Close-up of kid. He breathes in, instead of blowing out. Kid looks up at Mom again. She continues to hold hanky at his nose. Hanky flutters as kid blows out through his mouth. Kid looks up at Mom again. Kid looking sad. Cut to product. Cut to woman's hand with tablets. Woman's hand puts tablets in kid's hand. Dissolve to kid who's licking ice cream cone. Kid looks up, with ice cream on tip of nose. Cut to product."

THE GENERAL AUDIENCE

Recommendation: The techniques used to draw attention to parts of a commercial, and the weighting of the advocacy, indications for use and warning segments--be they audio or video--must be addressed by the FTC if it is to assure balance to the message.

There are aspects of advertising relevant to children which also affect the general public, particularly those with communication disabilities. In the FTC's Food/Nutrition hearings, we heard of the process of "cuing", whereby sophisticated designers of commercials direct the attention of the viewer to certain portions of the commercial message with much greater intensity than might be attributed to the message as a whole.

Cuing applies to the technical devices by which one can direct the viewer's attention to part or all of the screen. Samples of cuing are "balloons" such as those seen when characters are speaking in comic strips; eye movement from the principal in a picture to the person or product to which he wants to direct attention; arrows; large letters; loud noises; mood music; flashing lights; or even humorous actions or lines which are always followed by an action or statement with an element of surprise.

Cuing is obviously done in over-the-counter drug commercials when the video shot of the label gives greater emphasis to the name of the product than to the indications for use and warning. The advertiser wants the viewer's eye to pay attention to the name of the product. Cuing also occurs in drug commercials when the action is near the top of the screen while the advisory or cautionary language, including "Use only as directed," appears at the bottom of the screen.

In the Food/Nutrition hearings Dr. O'Bryan was asked about his eye movement studies and children.[18] He replied:

Q. Would you describe the difference between the preliterate child, the just literate child and the literate [child] as your eye movement studies show how words are read on the screen?

A. The preliterate child looks at the movement of a word if it moves. He doesn't read it because he can't. He may make an attack on the initial letter but it is clear from the eye movement study that no reading is taking place.

The just literate child who hasn't developed an avoidance pattern will examine the word and in some instances read it because he can develop the information and will try and link it to whatever visual factor is present on the screen.

The literate child will look at the words always first. The first thing that a reading child looks at on a television screen when a word appears is a word. They are most potent because we have learned the information retrieval system is from print. The producer nearly always sets it up so you would read it as well.

Q. Does the positioning of the word on the tube have any bearing on how much it is read?

A. To a large extent for the preliterate child it is a critical factor. For the child who has a learning difficulty or perhaps is reading at the Grade 2 level but may be in grade 5, it is an essential criterion to position a word properly. Otherwise the kid will avoid it. For the adult it is less critical.

You can certainly center the attention of the person more effectively by appropriate placement, but nearly always -- in fact always -- whenever a word which has salience to the action appears on the screen, it will be read by a reader regardless of its position. If you want the person to read it quicker and arrive at it in the shortest possible time, put it in the upper left-hand quadrant and you will find the quickest reaction to it. If you have a 10-second commercial and eight words, put them up there as far as you can and you will find they will get through them.

Q. Dr. O'Bryan, you have talked about cuing. Would I be correct that one can cue a child not to look at a portion of the screen?

A. Yes.

Q. If a disclaimer or other type of descriptive phraseology were written on the screen and the advertiser or sponsor did not want the child to pick up the message, can you describe the types of cues that would lead a child away from that disclaimer?

A. [Put it near] The bottom line quadrant. Bring action from the top left-hand quadrant. Move the action across the top of the screen and back to the bottom-left-hand quadrant. Virtually no one will look at the message.
I would like to return to a previous question of yours just to clarify the point on whether or not words would be read. I am assuming that no attempt is made to remove the attention from the word in that original question. If no direct cueing retrieval system of the person's attention is employed, then the word will be read, but if there is an overt attempt to distract attention from it, it could take up to five seconds or longer to have the person attend to the word.

Q. Would that apply to having white letters on a white background?

A. White letters on a white background would insure they couldn't read it because they couldn't see it."

Dr. O'Bryan's last quip seems curious until one examines how many advisories truly are white on a light background.

Since a large percentage of over-the-counter drug commercials either omit verbal directions (Exhibit A), highlight the label words in larger type above any warning or direction (Exhibit B), have upper level distractions when any directions appear in the bottom quadrant (Exhibit C), and go out of their way to merge such directions into the background (Exhibit D&E) we suggest that most drug commercials are masterful examples of how to focus the attention of the viewer, young or old, on the most affirmative parts of the sales message with the result that little or no attention is paid to any qualifying statements. *

For other examples we cite the FTC's submitted storyboards 6, 54, 72, 73, 122 and 130.

Repetition is an additional factor in over-the-counter drug advertising. In the Food/Nutrition hearings Dr. Samuel Ball and Dr. Kenneth O'Bryan spoke of the potential of repeated advertisements creating "overlearning" to the point where messages become hard to erase from the receptive mind. Overlearning primarily stems from repeated exposure to a message with clear and concise emphasis such as product name. The name is enhanced by being preceded by a cue and having a varied and interesting setting. But an unvarying message, uncued, placed in relative obscurity, by repetition may become so familiar as to be unread. In other words,

* See also FTC v. Hudson Vitamin Co. re "Spiderman"

while repetition of a single word may etch the product's name on the viewer's mind, repetition of phrases without variety can cause disattention. Repetition of the uncued phrase "Take only as directed" in hundreds of widely differing commercials showing strongly emphasized product names may soon cause the viewer to disregard that disclaimer or advisory. Call it "selective perception," or "selective obliteration"--the reaction is the same. There can be adverse repetition in a televised communication.

If over-the-counter drugs are advertised with synonyms for FDA-approved language, a subject on which we will have recommendations, and the warnings are locked into fixed language, the Federal Trade Commission may find the viewer paying less attention to the conditions of use or advisory messages than is desired.

A further area of concern stems from a phenomenon Robert B. Zajonc calls "Attraction, Affiliation and Attachment." Apparently mere repetition of single words can cause the listener to feel they are good or attractive. He says:

Supporting these correlational studies on exposure and attraction is also some good experimental evidence indicating that the attractiveness of a given stimulus object may be enhanced by virtue of its repeated exposure. Johnson, et al. (1960) have found that the semantic ratings of nonsense words can be enhanced when they are presented repeatedly. We have similar experience. A number of Turkish words were shown to our experimental subjects different numbers of times. Some words were seen by them frequently, others infrequently. These presentations were randomized such that each of the words appeared in different frequency for different subjects, and what word appeared on any one presentation was determined by chance. After viewing these words, the subjects were told that what they just saw were Turkish adjectives, and we unashamedly asked them to guess what the words they just saw meant. We proceeded to explain that we appreciated how nearly impossible this task was, given their lack of familiarity with Turkish. Nevertheless, we insisted that they try. To help our subjects guess these meanings we told them that each of these adjectives meant either something good or something bad, and that it was their task merely to guess for each Turkish word if it meant something good or something bad. Figure 4 shows the results of this experiment.

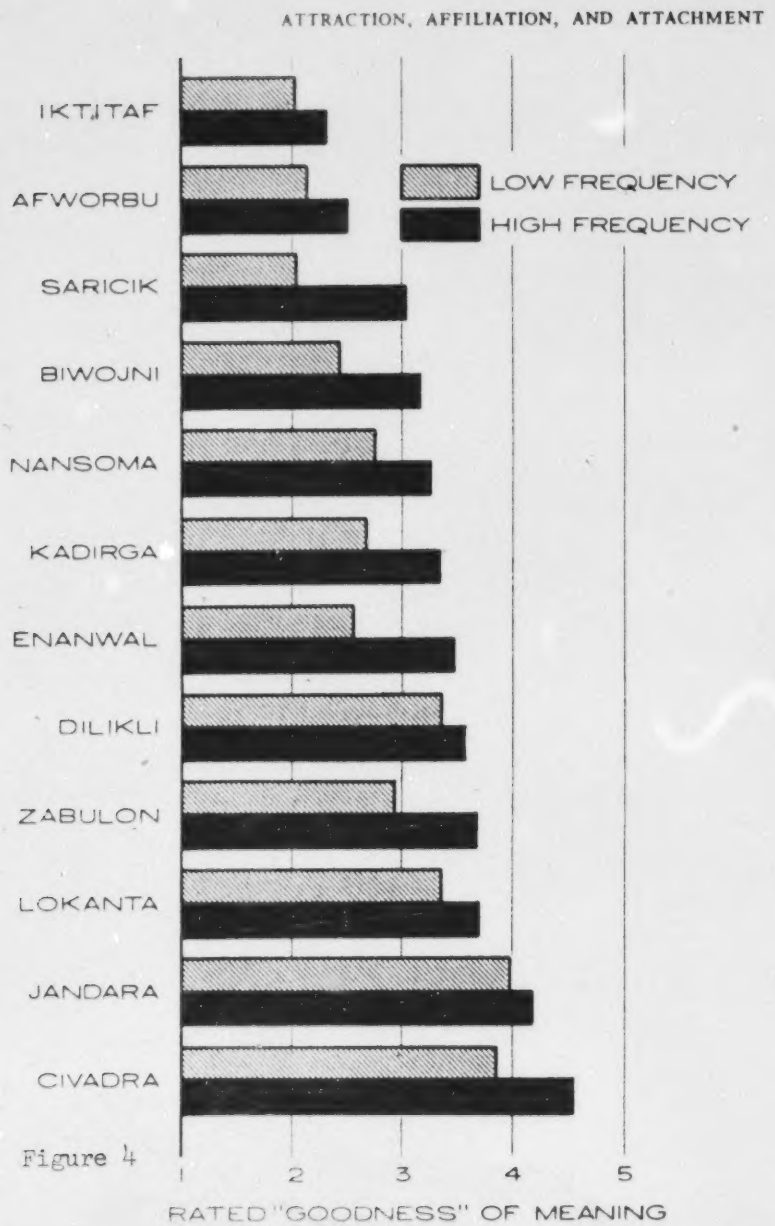


Figure 4

(We note how similar some of these words are to the names of over-the-counter drugs)

> The same experiment was replicated using different stimuli. Thus, for another instance, Chinese ideographs were substituted for Turkish words and used in the same manner. The subject first observed these ideographs in different frequencies and subsequently he was asked to rate their meanings. In the same way photographs of men's faces were exposed different numbers of times and the subjects were subsequently asked how much they liked them. Figures 5 and 6 show these results. While the comparisons for the ideographs and for the photographs are somewhat weaker than those found with the Turkish words, there are no reversals, and the overall effect still stands up. Out of a total of thirty-six comparisons, thirty-two favor a positive relation between frequency and liking, while four show no differences in liking as a function of previous experience. There is other evidence showing similar trends, but I will not describe it here.
>
> Currently we are studying some psychological processes which might explain why repeated exposure increases the attractiveness of the stimulus object. These processes are more fully outlined in my monograph on the effects of exposure (Zajonc 1968) and in a recent article by Harrison (1968). It suffices for present purposes to make a few observations. First, the effect of exposure is most pronounced when we expose the subject to novel stimuli. Secondly, the effects of exposure on attraction are logarithmic. That is, early exposures produce the strongest effects, while each successive exposure adds less and less to the total attractiveness of the object. Thirdly, the effect of exposure is easiest to demonstrate when the stimulus is emotionally neutral, and when exposures are not accompanied by other psychological events--such as stimuli that are noxious, positive, or negative reinforcers--or demands on subjects that they respond to the stimuli in some systematic way.19/

The average viewer of an over-the-counter drug commercial is remarkably ignorant of the growing sophistication of the communication. "Overlearning," "cuing," "reinforced for

his actions," "vicarious reinforcement reinforcing imitation," and "word attraction" are not common terms among those who watch television commercials, but the mental processes they describe affect most TV watchers of over-the-counter drug commercials a good deal of the time.

ALTERNATE LANGUAGE AND DESCRIPTIVE PHRASES

Recommendation: The Federal Trade Commission establish an office to weigh the public's understanding of the FDA's monograph language and to provide a hearing panel of behavioral scientists to which a sponsor can submit alternate language to that proposed by FDA. Any review of copy by such an office should ensure that the deviation from FDA language does not impair the purpose of any message relating to conditions for use, contraindications or warnings, nor place them in a subordinate role to the promotional scenario of the commercial. Further, the burden shall be on the sponsor to show that accredited and competent behavioral research proves that their alternate message is understood as well as, or better than, the FDA monograph language.

We believe some of the label language mandated by the FDA's monographs, if transposed to an advertisement, may not be fully comprehensible to the viewer of a television commercial. "Antiflatulence" and "antitussive" are not exactly household words. The Federal Trade Commission could establish a "lexicon of alternate phrases," but to do so it should first establish whether the public understands the alternatives any

better than the monograph language; or, the FTC could consider alternate language pre-submitted by the sponsors on a case-by-case basis. To do so, it again would have to have behavioral science evidence that the public understands the new phrases as well as or better than the FDA-mandated phrases.

Other considerations arise if advertising phrases are not confined to label language. An excellent example of this was Alka Seltzer's slogan "I can't believe I ate the whole thing." The Food and Drug Administration would not have permitted the label to say the product was a remedy for over-eating--yet that is the message the advertisement gave out. The commercial gave no facts about the ingredients or medical contraindications. The tablet, the package and the slogan said it all. Such reference to an event instead of an ailment can sell a product well, but never come close to a drug claim. We do not see how the FTC will address this type of promotion unless it constrains the language by which an over-the-counter drug is sold.

We also note that the FTC has not addressed itself to the grey area of adjectives and qualifiers such as "quicker acting," "more natural," "recommended by more doctors," "strong medicine," "gentle acting," or "helps relieve." The FDA panelists are concerned with this. The panel reviewing the over-the-

counter Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products stated (41 Fed. Reg. 38312, 28224 (1976)):

> The Panel is aware that the role of the Food and Drug Administration is to regulate labeling of over-the-counter drugs and the role of the Federal Trade Commission is to enforce adherence to such labeling in advertising. In addition to reconsidering specific labeling claims, warnings, and dosages, the Panel would like to make some general comments and recommendations regarding advertising of drugs.
>
> Advertisements extend the labels beyond the pharmaceutical counter or medicine cabinet. The public may well receive most of its attitudes toward CCABA [cold, cough, allergy, bronchodilator, and antiasthmatic] remedies from advertisements -- particularly television advertisements.
>
> For this reason the Board strongly urges the Federal Trade Commission to challenge any advertisement which:
>
> 1. In any way negates or dilutes the information on the label, especially the contraindications and/or warnings;
>
> 2. Suggests or leans heavily on words, phrases and portrayals that lead the lay person to assume that the product is to be used in any manner not recommended in the monograph established below, or that it cures when in reality it only alleviates symptoms.

> The Panel further recommends that advertisements for CCABA remedies not be placed where they can promote or suggest use by children, and if such an advertisement is placed where members of children may learn of the indications for the product, that such advertisement include clear and specific warnings and contraindications concerning child use.

Similarly, the Monograph for OTC Laxative, Antidiarrheal, Emetic and Antiemetic Products stated (40 Fed. Reg. 12902, 12904 (1975)):

> The Panel is of the opinion that there is widespread overuse of self-prescribed laxatives. Extensive advertising by the pharmaceutical industry has contributed to this problem. The Panel is aware that the FDA is limited in its jurisdiction to package labeling and not to advertising. However, the Panel is concerned that control of package labeling alone may be **insufficient** in assuring proper use of laxative agents. The Panel is hopeful that as a result of the review that all forms of advertising will be monitored by those having the appropriate jurisdiction, to insure that adequate warning and cautionary statements as found in product labeling will be carried over and incorporated in all advertising and promotional activities for these products.

Other monographs presently in draft form have similar comments.

If the expert panelists are concerned, the FTC should be.

The panelists' concern may have stemmed partly from parental considerations. If parents are misled by OTC drug advertisements, they will be less able to protect their children. If parents are not told of child indications for use, they will be unable to administer the proper drug. If they are not aware that many drug dosages are determined by body weight or years of age, they may administer the wrong amount.

We do believe parents should be the first line of defense for children. They should teach children the purpose of advertising in a private enterprise system, and provide them with the best means of analysing the truthfulness and completeness of every claim. To this end the Council (CCMM) has petitioned the major networks to run Public Service Announcements when children are in the audience to explain private enterprise, advertising's role therein, as well as the techniques used in advertising to make messages persuasive. Only in this way do we believe children and their parents can build an understanding of the various products, and of the total impact of viewing 20,000 - 25,000 TV commercials each year.

It is noteworthy that the three networks rejected this petition. When it was then referred to the Federal Communications Commission, the F.C.C. turned it down. 20/

THE PARENT-BROADCASTER ROLE

If a child views imprecise over-the-counter drug commercials, it really doesn't matter who plays the major drug advocate role in the home--the television set or the parent, for the chances are excellent that parents receive a large percentage of their over-the-counter drug information from drug commercials, and thus would be prone to pass that information on by actions or words when in the presence of the child, thereby seeming to reinforce the message. 21/

If the parent selects the over-the-counter drug for a child, (Exhibit F, See p. 32), or if the child sees a parent selecting an OTC drug for him/herself, (Exhibit G), or if the child sees a television model take a pill and relief is reflected in the subsequent period, (Exhibit H), the child receives a powerful message that this is appropriate conduct. Silence on the part of the parent when the child sees an OTC drug message also can be read by the child as approbation for the message. 22/

Throughout the development of drug advertising in front of children as a national issue, the business community has declared the issue to be a non-issue. They say parents have all the responsibility inasmuch as the broadcasters have declared drugs cannot be advertised to children. Analyzing this assertion, the aforementioned report to the National Science Foundation says:

> "Television advertising of proprietary medicines on 'children's programs' is prohibited by the National Association of Broadcasters Code:
>
> > 'Non-prescription medication regardless of how taken or administered shall not be advertised in or adjacent to programs initially designed primarily for children under twelve years of age.' (NAB, 1974).
>
> Similar provisions exist in the 'Children's Advertising Guidelines' issued by the National Advertising Division of the Council of Better Business Bureaus:
>
> > 'Medications, drugs and supplemental vitamins (liquid or pills) should not be advertised to children (BBB, 1975, p. 7).'"

But to clarify the weakness of these phrases, the report to the National Science Foundation goes on:

> "The National Association of Broadcasters guidelines apply to programs initially designed for children--that is, those shows which are concentrated on Saturday and Sunday mornings. Most children's viewing, however, occurs during late afternoon and early evening. The 'Children's Advertising Guidelines' of the Council of Better Business Bureaus pertain to advertising in children's programs and programs in which 'audience patterns typically contain more than 50% children.' These guidelines also apply when advertising is 'clearly addressed to children eleven and under.'"

We cite these statements to show the shallowness of the Code in its protection for children. Almost 90% of children's TV watching occurs other than weekend mornings.[23/] Children are seldom in a majority of the audience except on weekend mornings (Exhibits I & J). Thus the child-related

provisions of the Code do not apply to almost 90% of children's TV watching. The NAB has gone out its way to pretend it protects children from drug advertising. The Guidelines of the Council of Better Business Bureaus are similarly ineffectual.

Further evidence of the NAB's confusion over its child code's coverage was vividly revealed on February 22, 1977, when Tom Swafford, NAB's Vice President of Public Relations and Director of the Code Authority asserted to a Channel 9 (CBS) audience in Washington, D.C., that children cannot be shown in over-the-counter drug commercials. He said that the ads would not pass the NAB Code, and that they would not be aired. He continued to assert this position even in the face of evidence that the Congesperin commercial cited above currently was on the air in Washington and New York!

The masquerade of child protection by the NAB and CCCB is not new. It has been the subject of frequent Congressional hearings. In a petition to the Federal Communications Commission on April 10, 1975, entitled "Petition for Reconsideration and Redrafting of Amendments to Television License Renewal Form on Child Related Topics for Extension and Equalization of Restraints on Television Advertising to Children," we cited 76 over-the-counter drugs that were advertised on many of the top 40 television programs watched by children in a three week period. Many had no audio warning. (This amounts to over 1,000 over-the-counter drug commercials potentially being seen by children under 12 in the course of a year's TV watching.)

We also asked the FTC to remedy such fraudulent "protections" offered by the NAB in our formal petition of April, 1975 entitled "Petition to Issue a Trade Regulation Rule Governing the Private Regulation of Children's Television Advertising."

These TRR hearings are the only response we have had from the FTC on the subject. Children continue to see drug commercials.

IMPLICATIONS FOR ADULTS

> Recommendation: The FTC require 1) that all categories of over-the-counter drugs for which FDA monographs stress previous mis-statements or mis-indications carry some notice that both the product and the label now carry a corrected message, or 2) the FTC require a notice that all OTC drug product promotions are changing.

The massive amount of over-the-counter drug advertising on the nation's airways seemingly has invited an electronically induced national hypochondria. In the regular promotion of tranquilizers, analgesics and sleeping products for those who are restless at night or nervous the issue of course is that restlessness at night may not be an unnatural problem. The older one gets, the less one needs sleep. Tension is natural under certain provocative conditions. When one sees massive amounts of laxative advertisements, the suggestion is of a biological abnormality--an ailment; but as the FDA monograph authors pointed out, irregularity of bowel movement is not a sign of an ailment. The promotion of many products, particularly over television, have made such common physical characteristics appear to be a problem.[24] As Alistair Cooke put it:

> "The thing that bothers me most about commercials is the medical brainwashing that the family gets on television. It seems to me that it easily outweighs any lessons in chemistry or biology that the child picks up in school...The body of our knowledge about medicine is fed to us from a very early age by commercials--and it's idiotic medicine. Mostly, it's either harmful or useless."

In the case of adults, products that have been advertised for years over national television will continue to carry the image of being "problem relievers" even though this and other FTC/OTC rules will restrain advertising language. Unless the public is notified that something meaningful has brought change to the product and label, the public may continue to believe all the problem-related characteristics which have been popularized in the past.

Beliefs in folk remedies raise another potential vulnerability. Advertising of old fashioned "curealls" lent certainty that bitters, flowers of sulphur, sweet spirits of mitre and a host of such labeled "chemicals" really have some special qualities.

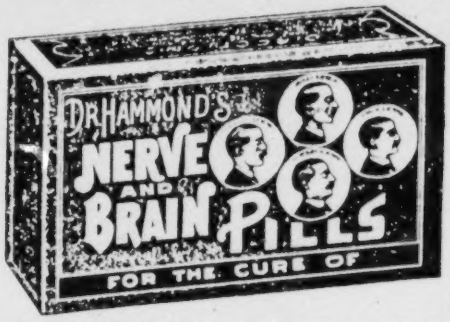
In 1902, over-the-counter drugs advertised miraculous cures:

Dr. Hammond's Nerve and Brain Pills.

GUARANTEED THE HIGHEST GRADE ON THE MARKET.

A BOON FOR WEAK MEN.

In full price $1.00
Our price, each $0.60
Our price, per dozen 6.00



SIX BOXES POSITIVELY GUARANTEED TO CURE ANY DISEASE for which they are intended. This will cure you if you feel generally miserable or suffer with a thousand and one indescribable bad feelings, both mental and physical, among them low spirits, nervousness, weariness, lifelessness, weakness, dizziness, feeling of fullness like bloating after eating, or sense of goneness or emptiness of stomach in morning; flesh soft and lacking firmness, headache, blurring of eyesight, specks floating before the eyes, nervous irritability, poor memory, chilliness, alternating with hot flushes, lassitude, throbbing, gurgling or rubbing sensations in bowels, with heat and nipping pains occasionally; palpitation of heart, short breath on exertion, slow circulation of blood, cold feet, pain and oppression in chest and back, pain around the loins, aching and weariness of the lower limbs, drowsiness after meals but nervous wakefulness at night, languor in the morning, and a constant feeling of dread, as if something awful was going to happen.

IF YOU HAVE ANY OF THESE SYMPTOMS our NERVE AND BRAIN PILLS will cure you. No matter what the cause may be or how severe your trouble is, DR. HAMMOND'S NERVE AND BRAIN PILLS will cure you. These pills have a remarkable effect on both old and young. They cannot be equaled by any other medicine as a cure for impotency, spermatorrhœa, night sweats, emissions, varicocele (or swollen veins), weakness of both brain and body arising from excesses and abuses of any kind. They will tone up the whole nervous system, no matter how much worn out, overworked or depressed you may be; the weak and timid young man made strong and bold again; they will give youthful vigor and a new lease of life to the old.

BEWARE OF QUACK DOCTORS who advertise to scare men into paying money for remedies which have no merit. Our Nerve and Brain Pills are compounded from a prescription of one of the most noted German scientists, and are the same as have been used in German hospitals for years with marvelous success. HOW TO CURE YOURSELF and full and explicit directions are enclosed with every box. All orders and inquiries concerning these pills will be treated confidentially, and all shipments made in plain sealed package.

Advertising of just a few years ago was only a bit less far-fetched:

From Parade Magazine March 28, 1971

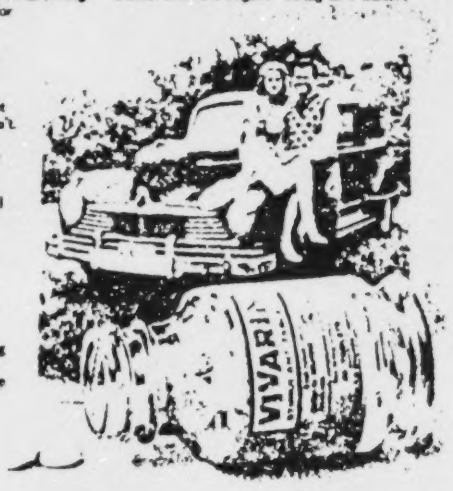
"One day it dawned on me that I was boring my husband to death."

When you're married as long as I am, you can reach a point where you start taking your husband for granted. Good old dependable Jim I used to say, and I guess that's how he was beginning to think of me, too. Good old dependable Barbara. It was horrible.

One day it dawned on me that I was boring my husband to death. It was hard for me to admit it—but it was true. It wasn't that I didn't love Jim, but often by the time he came home at night I was feeling dull, tired and drowsy. And so Jim would look at television and, for the most part, act like I wasn't even there. And I wasn't.

I decided that I had to do something. I had seen an advertisement for a tablet called Vivarin. It said that Vivarin was a non-habit forming stimulant tablet that would give me a quick lift. Last week there were a couple of evenings when I felt that I needed Vivarin. So, on those days, I took a Vivarin tablet at 5:00 p.m., just about an hour before Jim came home, and I found time to pretty up a little, too. It worked.

All of a sudden Jim was coming home to a more exciting woman, me. We talk to each other a lot more than we have in years—like we used to when we first were married and we'd take long rides in the old car just to be together and talk. And after dinner I was wide awake enough to do a little bit more than just look at television. And the other day—it wasn't even my birthday—Jim sent me flowers with a note. The note began: "To my new wife..."



Advertising of modern-day products continues to lead the public to believe more in a product that it can deliver.* Many believe that an antibacterial soap kills all germs--it

* See FTC v. Warner-Lambert in the "Listerine" case

does not. Others believe that very strong laxatives, sometimes called purgatives, can "straighten out" an upset system. And of course there are those women who believe that feminine douches prevent pregnancy or are sufficiently antibacterial to stop infection--they don't.* In many instances these beliefs or myths were fostered by past advertising; the susceptibility of the lay public, when combined with the en masse effect of today's problem-related OTC advertising, suggests that those who seek to shape OTC drug advertising must develop a national awareness that the new language for OTC drug labels and advertisements is precise, and accurately describes the real conditions for which the new product has merit.

SPECIAL CONSTITUENCIES

> Recommendation: Any conditions for use and warning be in audio and video form so that those with sight or hearing impairments may have equal opportunity to understand the merits and limits of the product, and conditions for safe and effective use.

Among our constituents are those who cannot hear. They live in normal houses, sometimes with others who cannot hear, and sometimes with those who can hear. Television is no stranger. But any part of the sales message that

* See Doris Savitch 50 FTC, 828 (1954)
affirmed Doris Savitch v. FTC, 218 F.2d 817 (2d.Cir. 1955)

deals with conditions of use and contraindications which is in sound only totally escapes the attention of such citizens. There may be 14,000,000 individuals in the United States with hearing sufficiently impaired to result in an inability to pick up the total OTC message. For them, indications for use, contraindications and warnings must be given equal highlight in the video portion of the message. Equal highlights must include all those conditions of cuing which Dr. Kenneth G. O'Bryan's remarks related to earlier in our statement. A number of storyboards of commercials reveal how subordinated are such phrases as "Take only as directed," or "Read the label." (Exhibit A, B, C, D, E)

The Federal Trade Commission took special note of the vulnerability of the deaf in its Hearing Aid hearings. In its Statement of Reasons for the hearings, the FTC said the deaf are "often particularly subject to and the victims of a wide variety of selling abuses." (40 Fed. Reg. 26651)

Dr. Aimee D. Leifer, a researcher at Harvard's Center for Research in Children's Television, points out that there is good evidence that the combination of audio and video messages to children have much greater impact than messages using only one technique.[25/]

The nation's blind apparently "watch" a great deal of television. The National Federation of the Blind suggests that the blind are really like all the rest of us, and that television's plots often do not require sight to be understood. But for those with impaired eyesight, any instructions for use which are shown visually but are not backed up by an audio message effectively conceal critical facts. The blind also do not have reference to the label instructions by themselves; they can not read package inserts. While they may often turn to their sighted friends for a reading of the instructions, it is probable that much of the knowledge they hold of OTC drugs stems from airwave communications. Thus audio completeness of communication becomes extremely important. Not many over-the-counter drug commercials have audio indications for use or warning instructions. Radio commercials often omit the whole subject. (Exhibit FTC#5, #6 and #30)

It is obvious that adults with reading disabilities would gain when conditions for use and warnings are in both video and audio as over-the-counter drugs are advertised over the air.

There is ample research which indicates the high degree of learning which takes place among the not fully educated as they are exposed to repeated tape and film messages.[26/]

SUMMARY

- Over-the-counter drugs are changing, in their ingredients and in their labels; the Food and Drug Administration's timetable is very different from the Federal Trade Commission's timetable;
- The public is probably unaware that the changes are occuring and that the changes are meaningful;
- The public probably is unaware that the proposed FTC Trade Regulation Rule on Over-the-Counter Drug Advertising will bring substantive change to those advertisements;
- Advertisements are not just highly visible labels, and the language of one may not be exemplary for the other; at the same time, labels are frequently shown in advertisements;
- Advertising of OTC drugs is big business; the public is unaware of the sophistication of the typical commercial on television; children, illiterates, the deaf and the blind see a great many OTC drug commercials;
- Commercials on television can highlight parts of a message; certain words can become regarded as good merely through repetition; advisories can be subordinated;

- Alternate language to that in the FDA monographs may be necessary for general public understanding; the FTC needs to provide a mechanism to weigh such alternate phraseology;

- The FTC must address itself to the grey area of adjectives and qualifiers for OTC drug messages;

- The FTC TRR on OTC drug advertising needs amendment and change to be effective.

CONCLUSION

We hypothesize that familiarity with a label in a television commercial, particularly if it is unfocused as to some of its critical content, invites contempt or disinterest in the label when the viewer finally has an opportunity to absorb the information at hand. If this concept does occur, the prospective purchaser, previously persuaded that the product is worthy and useful, will not be led by the commercial to appreciate the strict new verbiage laid down by an FDA monograph unless major reform of OTC drug advertising occurs, particularly in television.

Many of the arguments raised in this statement can be explored by competent behavioral research. The real impact of advertising using the FDA approved language should be

tested, if only to provide a basis for judging alternate phraseology which sponsors may want to offer in court challenges. The FTC should have an on-going capability to judge the balance in product advocacy vs. indications for use and warnings. It also should have a continuing ability to weigh the utility of warnings, particularly to children. To carry out these responsibilities, and to honestly evaluate alternate messages submitted by sponsors, we suggest the Congress strengthen the research arm of the FTC, and improve the agency's understanding of the public's comprehension of advertising messages.

The very revision of the contents and the label by FDA will be considered by some to sanctify the product. If the Federal Trade Commission goes through this massive Trade Regulation Rulemaking process, the advertising slogans and depictions will be further sanctified; the drug industry will be certain to point out quickly to the public that major governmental reviews have attested that both the products and the messages are warranted for all concerned.

Because of this sanctification, because of the reforms that have actually taken place in the products and the labels, and because the public has been misled in the past by unbalanced advertisements for innumerable over-the-counter drug products which resulted in unfair and deceptive practices on the consumer, we believe the following amendments and modifications to the TRR should take place.

TECHNICAL RECOMMENDATIONS

We propose an interim statement be placed in all over-the-counter drug advertising upon finalization of this particular OTC drug advertising rule. The interim statement would be terminated category-by-category when the FTC's accompanying TRR on warnings for a particular category is finalized:

Therefore we suggest:

§450.1(c)

> All advertisements for over-the-counter drugs shall state upon adoption of this rule:
>
> > The government is reviewing non-prescription drugs, labels and advertisements. As some are changing, read the label directions carefully.

In addition, to implement the aforementioned discussion, the final Trade Regulation Rule at issue should be amended to include the following points:

§450.1(d)(1)

> No over-the-counter drug commercial may be shown before 9:00 p.m. within or near a national television program when there is reasonable expectation the audience under

12 (twelve) years of age exceeds 2,000,000 or 50%, whichever is the lesser, unless an effective warning against use by children that is comprehensible to children over four years of age is included.

(2)

No over-the-counter drug commercial may be shown within or near a television program aired primarily under local control if the audience under 12 (twelve) years of age reasonably can be expected to exceed 10% of the locally available TV households according to A. C. Neilsen or Arbitron in that market area.

§450.1(e)

Any advertiser who can provide behavioral science documentation which substantiates that alternate depictions, graphics or phrases to that language set forth in the FDA monograph is equally or better comprehended by the lay public, including individuals of low comprehension under customary conditions of observing advertising, shall have a right of petition to an Advertising Review Panel of behavioral science peers chosen by the FTC from a roster of accredited professionals. The panel shall submit its recommendation to the Bureau of Consumer Protection. The Bureau shall then make a determination whether the message may be accepted for later use in the public media.

§450.1(f)(1)

Conditions for use and warnings must be in all OTC drug advertising.

(2)

No part of an advertisement for an over-the-counter drug may declare the conditions of usage, warnings o contraindications, or of any change of ingredient, label or advertisement status in any position or condition which subjects such message to an inferior position (when seen, heard or absorbed by the public to that portion of the message which stresses the label, package or product in an affirmative manner. All such usage, warning or contraindication or change of status messages on television shall be simultaneous in both audio and video.

Note: Professional oral testimony pertinent to the above remarks may be presented by the National Center for the Law and the Deaf, a representative of the blind, and Dr. Charles Atkin.

As this goes to press, a number of storyboards and kinescopes are in transit. They will be included in the exhibits, and linked to the appropriate argument in a cover letter to all interested parties. The kinescopes will be on file at the FTC, and will be viewable at the office of the Council at 9 AM on March 11 & 14.

LEGAL RESPONSIBILITIES

Both the Federal Communications Commission and the Federal Trade Commission have obvious responsibilities to protect those who have communication disabilities. Children are first among these. Those with other communication problems also warrant special government attention. We here repeat the arguments made in behalf of children in the Food/Nutrition Rule hearings; we add legal citations undergirding protection for the illiterate and those with hearing and sight impairments.

As a starting premise we note that most commercial law is based on the concept of a reasonably prudent consumer interacting with those who sell. But children, almost by definition, are reasonably imprudent. Thus in a commercial transaction special precautions must be taken to avoid an unfair or deceptive practice.

With younger children the very existence of a commercial's selling intent may not be understood.[27]/

The Federal Communications Commission in its 1974 "Children's Television Programs - Report and Policy Statement", a document which reflects four years of consideration, strongly set forth the Commission's concern with advertising seen by children: [28]/

30. Traditionally, however, the Commission has not attempted to exercise direct supervision over all types of advertising abuses. Since the Federal Trade Commission has far greater expertise in, and resources for, the regulation of false or deceptive advertising practices, the FCC has largely confined its role in this area to notifying stations that the broadcast of material found to be false or deceptive by the FTC will raise questions as to whether the station is operating in the public interest. See Public Notice entitled "Licensee Responsibility with Respect to the Broadcast of False, Misleading, and Deceptive Advertising, FCC 61-1316 (1961); "Consumers Association of District of Columbia," 32 FCC 2d 400 (1971). We do not believe that it would be appropriate to change this policy at the present time. The Federal Trade Commission is currently conducting inquiries into advertising practics on children's programs (F.T.C. File No. 7375150) and food advertising (F.T.C. File No. 7323054) which cover many of the advertising practices objected to by the parties before the Commission. In light of the actions of the FTC, we have chosen not to address some of these specific promotional practices. On the basis of this proceeding, however, we are persuaded that an examination of the broadcaster's responsibility to children is warranted in the areas of the overall level of commercialization and the need for maintaining a clear separation between programming and advertising.

34. If our policy against overcommercialization is an important one, and we believe that it is, it is particularly important in programs designed for children. Broadcasters have a special responsibility to children. Many of the parties testified, and we agree, that particular care should be taken to insure that they are not exposed to an excessive amount of advertising. It is a matter of common understanding that, because of their youth and inexperience, children are far more trusting of and vulnerable to commercial "pitches" than adults. There is, in addition, evidence that very young children cannot distinguish conceptually between programming and advertising; they do not understand that the purpose of a commercial is to sell a product. See Report to the Surgeon General, "Television and Growing Up: The Impact of Televised Violence," Vol. IV at 469, 474 (1970). Since children watch television long before they can read, television provides advertisers access to a younger and more impressionable age group than can be reached through any other medium. See "Capital Broadcasting Co., supra," at 585–6. For these reasons, special safeguards may be required to insure that the advertising privilege is not abused. As the Supreme Court stated, "[i]t is the interest of youth itself, and of the whole community that children be . . . safeguarded from abuses." "Prince v. Massachusetts," 321, U.S. 158, 165 (1943).

While defering to the FTC on advertising content, the FCC made some pointed comments on the role television should play with children. The remarks were primarily aimed at programming, but obviously carry over into the general commercial area.

16. As we have long recognized, broadcasters have a duty to serve all substantial and important groups in their communities, and children obviously represent such a group. Further, because of their immaturity and their special needs, children require programming designed specifically for them. Accordingly, we expect television broadcasters as trustees of a valuable public resource, to develop and present programs which will serve the unique needs of the child audience.

17. As noted above, the Federal Radio Commission and the Federal Communications Commission have consistently maintained the position that broadcasters have a responsibility to provide a wide range of different types of programs to serve their communities. Children, like adults, have a variety of different needs and interests. Most children, however, lack the experience and intellectual sophistication to enjoy or benefit from much of the non-entertainment material broadcast for the general public. We believe, therefore, that the broadcaster's public service obligation includes a responsibility to provide diversified programming designed to meet the varied needs and interests of the child audience.

18. In this regard, educational or informational programming for children is of particular importance. It seems to us that the use of television to further the educational and cultural development of America's children bears a direct relationship to the licensee's obligation under the Communications Act to operate in the "public interest." Once these children reach the age of eighteen years they are expected to participate fully in the nation's democratic process, and, as one commentator has stated:

> Education, in all its phases, is the attempt so to inform and cultivate the mind and will of a citizen that he shall have the wisdom, the independence, and, therefore, the dignity of a governing citizen. Freedom of education is, thus, as we all recognize, a basic postulate in the planning of a free society. A. Meiklejohn, The First Amendment is an Absolute, in 1961 Supreme Court Review 245, 257 (Kurland ed.); see generally Brennan, The Supreme Court and the Meiklejohn Interpretation of the First Amendment, 79 Harv. L. Rev. 1 (1965).*

We believe that the medium of television can do much to contribute to this educational effort.

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*In the words of the Supreme Court, "[a] democratic society rests, for its continuance, upon the healthy, well-rounded growth of young people into full maturity as citizens, with all that implies." Prince v. Massachusetts, 321 U.S. 158, 168 (1943).

When it came to helping the FTC in these regards, though, the FCC proved to be a paper tiger. The FTC at one point sought the airing of educational commercials. The FCC opposed them. When this Council, CCMM, recently sought to balance commercials with information about their techniques, the FCC rejected our petition. Thus it seems clear that the FCC has declared children to be vulnerable, but that in advertising the FTC has the prime responsibility.

The FTC has a clear mandate to protect children. Ex-Chairman Lewis Engman recognized this in his testimony before the Senate Commerce Committee, FTC Oversight, March 14, 1974. He said:

> I think that the law historically has recognized that children are treated differently. There are different standards, standards that are applied with respect to criminal prosecutions, with respect to our whole juvenile court system, and with respect to a host of other areas in the law.

Because most of the advertising to which children are exposed comes through licensed television communication, the legal rights of children face examination from several quarters.

We have reprinted many of the most pertinent aspects of FTC decisions on previous pages of this testimony. The principal cases seen to be:

Prince v. Massachusetts, 321, U.S. 158,168 (1953)

Capital Broadcasting Co. v. Mitchell 333 F. Supp 582,584 (1971); aff'd 405 U.S. 1000

Topper Corporation, 21 FCC 2d. 148 (1969)

American Broadcasting Co., 23 FCC 2d. 132 (1970)

It is interesting to note that among comments filed on the FCC's "Children's Television Programs--Report and Policy Statement" in 1974, broadcasters had very specific views about the responsibility of various Federal agencies. In a footnote to a paragraph summarizing certain industry practices, the FCC states:

> In this regard, it should be noted that to the extent broadcasters agreed that government intervention in the realm of advertising was appropriate at all, they considered the Federal Trade Commission to be the appropriate agency to handle this function. Some licensees thought the FTC was overzealous;none of them considered it too timid or inadequate to the task.

It must also be noted that the FCC had a rather narrow interpretation of children's programs--defining those as when children were in a majority of the audience--and thus the question of protecting large numbers of children in an audience when not a majority still had to be addressed. The FCC's policy statement acknowledges children's need for protection from certain advertising practices, but defers most responsibility to the FTC.

As to the FTC's own responsibility in regard to children as part of the general public, a number of cases seem pertinent. The Commission clearly stated its special concerns for children and advertising (even of an "adult" product) in its "Statement of Basis and Purpose of Trade Regulation Rule 408" dealing with cigarette advertising. The Commission said:

> ***(T)hroughout the law in general and under section 5 of the Federal Trade Commission Act in particular, it has been recognized that minors constitute an especially vulnerable and susceptible class requiring special protection from business practices that would not be unlawful if they only involved adults. Accordingly, a marketing practice, directed in a substantial part toward minors, that interferes substantially and unjustifiably with their freedom of buying choice is an unfair or deceptive act or practice even if it is not especially pernicious as to adults.

A more comprehensive review of pertinent FTC cases bearing on this Rulemaking procedure can be found in the Appendix.

An obscenity related case also stressed that children were to be considered even if they were not the majority group to be affected. See Ginsberg v. New York, 390 U.S. (1968).

There are other cases that primarily deal with the issues raised by certain groups' vulnerabilities. The FTC recognized its responsibilities to the deaf in the recent

Hearing Aid rulemaking. As part of its Statement of Reasons the FTC recognized the deaf are "often particularly subject to and the victim of a wide variety of selling abuses." (40 Fed. Reg. 26651)

In regard to vulnerable groups in general the courts recently have held that the elderly warrant special protections since they are less able to move around.

> Va. State Board of Pharmacy v. Va. Citizens Consumer Council, 44 U.S. L.W. 4686 (May 24, 1976)

In regard to those with language communication difficulties the FTC in a consent agreement relating to the advertising of cigarettes in a Spanish language area (Puerto Rico) required that warnings be in the native tongue.

From the standpoint of the FDA and its power to back-up the FTC in such matters we refer to Alberty Foods Products v. U.S. 185 F 2nd 321; Ninth Circuit 1950. In this instance the courts held that the FDA had the power to seize a product because the advertising suggested far more than the product's label, and hence misrepresented the product. FDA's power to seize when an advertisement departs from a label's strict language gives the Federal Trade Commission a much stronger hand in establishing proper drug advertiser practices.

REFERENCES

1/ Senate Hearings, "Advertising of Proprietary Medicines, Part I," May 25-25 and June 15-17, 1971.

2/ Gardner, Sherwin, "Statement of the Commissioner of Food and Drugs in Federal Trade Commission Rulemaking Proceeding on Over-the-Counter Drug Advertising," statement submitted January 5, 1977; (Rule No. R-511009)

3/ Ibid.

4/ Robertson, T. S. and Rossiter, J. R., "Short-Run Advertising Effects on Children: A Field Study," Journal of Marketing Research, Vol. XIII (Feb. 1976), 68070.

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6/ Advertising Age, November 15, 1976, p. 70, "Early Demographic Leaders."

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11/ Kanter, loc cit.

12/ Robertson, Thomas S., and Rossiter, John R., "Children and Commercial Persuasion: An Attribution Theory Analysis," Journal of Consumer Research, Vol. 1 (June 1974), pp. 13-20.

13/ Liebert, loc cit.

14/ Council on Children, Media and Merchandising and Swankin and Turner, Petition to Issue a Trade Regulations Rule Governing the Private Regulation of Children's Television Advertising, Federal Trade Commission, May, 1975.

15/ Flanders, James P., "A Review of Imitative Behavior," Psychological Bulletin 69;316-337, 1968.

16/ Personal communication.

17/ Personal communication.

18/ O'Bryan, loc cit.

Hearing Report, Consumer Subcommittee of the Committee on Commerce, United States Senate, 93rd Congress, 1st Session, Serial No. 93-9; February 26-27, 1973.

19/ Zajonc, loc cit.

20/ Memorandum Opinion and Order, Docket No. 19142, released February 3, 1977, Federal Communications Commission.

21/ Courtney, loc cit.

22/ Liebert, Robert M., Statement before the U.S. House of Representatives Subcommittee on Communications of the Committee on Interstate and Foreign Commerce, Serial No. 94-53, July 16, 1975.

23/ Children's Television Programs--Report and Policy Statement, Federal Communications Commission, Fed. Reg. Vol. 39, No. 215, Nov. 6, 1974.

24/ Courtney, loc cit.

25/ Leifer, loc cit.

26/ Schramm, loc cit.

Liebert, loc cit.

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Holaday, loc cit.

Rossiter, loc cit.

Leifer, loc cit.

Courtney, loc cit.

27/ Robertson, loc cit.

28/ Children's Television Programs, loc cit.

EXHIBITS: As identified in testimony and in appendix section.

Also: Exhibit K shows deprecation of "occasional use, as directed".
Exhibit L shows child in a drug commercial.
Exhibit M shows model's relief within 30 second commercial - hence a reward.
Exhibit N demonstrates Package identification.

All exhibits show use of an advisory message which does not refer to any specific instructions elsewhere.

EXHIBIT LIST

Exhibit A_1--Dristan Nasal Mist--Three Handkerchiefs
Exhibit A --Anacin--Your Body Knows (diagram)
Exhibit B --Anacin--Arthritis Pain--(woman making bed--diagram)
Exhibit B_1--Momentum--Man With Muscular Backache--(diagram of muscle)
Exhibit C --Dristan--Hayfever--(woman and child on bicycle)
Exhibit C_1--Contac--This is Pollen--(magnified pollen)
Exhibit D --Dristan Nasal Mist/Vapor Spray--Congested man (diagram of sinuses)
Exhibit E --Bayer Aspirin--The First Signs of a Cold--(different people taking at different times for different ailments)
Exhibit G --Dristan--It's Flu Season
Exhibit H_1--Anacin--Grandmother's Arthritis on Sarah's Christening Day--(freedom of movement chart)
Exhibit H_2--Excedrin--It's the ...sort of pain that...
Exhibit I --Summary
Exhibit J --Neilsen Rating
Exhibit K --Duration Nasal Spray--(2001 Space Odyssey--The Big 12)
Exhibit L --Congespirin--(little boy has sniffles)
Exhibit M --Nytol--Bright Eyes--(woman and man doing commercial--yawning)